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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,921	05/23/2001	John C. Reed	P-LJ 4752	1677

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT PAPER NUMBER

1634

DATE MAILED: 09/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/864,921

Applicant(s)

REED ET AL.

Examiner

Jeffrey Fredman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-8, drawn to nucleic acids, classified in class 536, subclass 23.1.
  - II. Claims 9-11, 27, 29, drawn to proteins, classified in class 530, subclass 350.
  - III. Claims 12, drawn to methods of producing proteins, classified in class 435, subclass 69.1.
  - IV. Claims 13-16, 27, drawn to antibodies, classified in class 530, subclass 387.1.
  - V. Claim 17, drawn to hybridization assays, classified in class 435, subclass 6.
  - VI. Claims 18, 26, drawn to immunoassays, classified in class 435, subclass 7.1.
  - VII. Claims 19-21, 30, drawn to methods of screening for Card related molecules, classified in class 436, subclass 501.
  - VIII. Claims 22-25, drawn to gene and antisense therapy methods, classified in class 514, subclass 44.
  - IX. Claim 28, drawn to protein therapy methods, classified in class 424, subclass 184.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions in Groups I, II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because the products of each Group differ in structure, function and effect, have different modes of operation, and yield different results. Specifically, the proteins of Group II are polymers composed of amino acids which have specific inhibitory or activating activities based upon their three dimensional folded structure and act to effect the retinoic acid pathway directly. These molecules can be used for further screening assays or for enzymatic assays on protein function. The nucleic acids of Group I have an entirely different chemical structure, being composed of nucleotides, and operate by hybridization and by serving as a information template. Finally, the antibodies of Group IV are specific binding molecules which differ in structure and function from both the nucleic acids of Group I and the proteins of Group II since the antibodies function by specific interaction of VDJ domains to specifically interact and detect another molecule.

3. Inventions in Group II and in Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the protein can be produced by expression as in the method of Group III or by chemical synthesis.

4. Inventions in Group I and in Groups III, V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used in protein expression, in gene therapy, in hybridization detection, or in nucleic acid purification or amplification assays.

5. Inventions in Group II and in Groups VI, VII, and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the proteins can be used in immunoassays as in Group VI, in screening methods as in Group VII, in protein therapy methods as in Group IX, or in antibody generation methods, in enzymatic assays.

6. Inventions in Group IV and in Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody can be used in the immunoassay method of Group VI, in antibody therapy methods, or in protein purification methods.

7. Inventions III, V, VI, VII, VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are unrelated because each method differs from each other method in mode of operation, function and effect. For example, Group III is a method of expressing proteins using cell expression systems which results in a protein, while Group V is a method of nucleic acid hybridization in which nucleic acids are mixed to interact and result in a hybridization product which can be detected. Each of the methods uses different reagents and gives different results.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. This application contains claims directed to the following patentably distinct Restriction Subgroups of the claimed invention. After election of one of the Groups above, Applicant is required to also elect a restriction subgroup. This is not a species election. Each Sequence is structurally and functionally distinct. Applicant will be required to cancel non-elected subject matter upon indication of allowable subject matter.

Subgroup I – SEQ ID NO: 12

Subgroup II – SEQ ID NO: 168

Subgroup III – SEQ ID NO: 188

Subgroup IV – SEQ ID NO: 170  
Subgroup V – SEQ ID NO: 172  
Subgroup VI – SEQ ID NO: 174  
Subgroup VII – SEQ ID NO: 176  
Subgroup VIII – SEQ ID NO: 97  
Subgroup IX – SEQ ID NO: 99  
Subgroup X- SEQ ID NO: 101  
Subgroup XI - SEQ ID NO: 103  
Subgroup XII - SEQ ID NO: 178  
Subgroup XIII - SEQ ID NO: 180  
Subgroup XIV – SEQ ID NO: 182  
Subgroup XV – SEQ ID NO: 184  
Subgroup XVI – SEQ ID NO: 86  
Subgroup XVII – SEQ ID NO: 90  
Subgroup XVIII – SEQ ID NO: 11  
Subgroup XIX – SEQ ID NO: 167  
Subgroup XX – SEQ ID NO: 187  
Subgroup XXI – SEQ ID NO: 169  
Subgroup XXII – SEQ ID NO: 171  
Subgroup XXIII – SEQ ID NO: 173  
Subgroup XXIV – SEQ ID NO: 175  
Subgroup XXV – SEQ ID NO: 96

Subgroup XXVI – SEQ ID NO: 98

Subgroup XXVII - SEQ ID NO: 100

Subgroup XXVIII – SEQ ID NO: 102

Subgroup XXIX - SEQ ID NO: 177

Subgroup XXX – SEQ ID NO: 179

Subgroup XXXI – SEQ ID NO: 181

Subgroup XXXII – SEQ ID NO: 183

Subgroup XXXIII – SEQ ID NO: 85

Subgroup XXXIV – SEQ ID NO: 89

Applicant is required under 35 U.S.C. 121 to elect a single disclosed Subgroup for prosecution on the merits to which the claims shall be restricted.

Applicant is advised that a reply to this requirement must include an identification of the restriction subgroup that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the Restriction Subgroups are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the Restriction Subgroups to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.



10. A telephone call was made to Melanie Webster on September 15, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

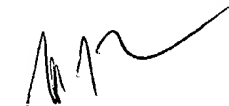
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman  
Primary Examiner  
Art Unit 1634